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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/804,107	03/12/2001	Robert M. Scribner	1759.15100-DIV	8986

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EXAMINER

PHILOGENE, PEDRO

ART UNIT	PAPER NUMBER
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3732

DATE MAILED: 08/26/2002

#11

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/804,107

Applicant(s)

SCRIBNER ET AL.

Examiner

Pedro Philogene

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 6/3/02.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-201 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) See Continuation Sheet is/are rejected.
- 7) ☒ Claim(s) 38,75-78,84,92-95,101,108-111,116,124-126,131,138-141 and 145-195 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 09. 6) ☐ Other: _____

Continuation of Disposition of Claims: Claims rejected are 63,64,66,67,69-74,79-83,85-91,96-100,102-107,112-115,117-123,127-130,132-137,142-144 and 196-201.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 63-201 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-21 of U.S. Patent No. 6,241,734. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference between these two sets of claims is that in the present application a nozzle instrument is omitted. Clearly, applicant is attempting to obtain broader coverage in the claim of the present application. Thus, the patent is considered as prior art. As transitional phrase "comprising", the claim of the patent and the claim of the application both cover all of the elements of an apparatus for delivering material into bone – that is the cannula, the delivery device, the nozzle instrument, and the tamping instrument. Thus the controlling fact is that patent protection for the apparatus for delivering material into bone, fully disclosed in and covered by the claims of the patent, would be extended by the allowance of the claims in the present application; and as already stated, nothing prevented applicant from

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presenting the claims in the application for examination during the prosecution of the issued patent.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 63,64,66,67,69-73,113,114,128,129,132-136,142-144 are rejected under 35 U.S.C. 102(e) as being anticipated by Moskovitz et al. (5,741,261).

With respect to claims 63,113,128, Moskovitz et al disclose an apparatus for delivering material into bone (110) comprising a cannula (111) for establishing a subcutaneous path into bone and a tamping instrument (120) having a tamping terminus (FIG.21); the tamping instrument (120) being sized and configured for manipulation independent of the cannula to urge material residing in the cannula into bone, and withdrawal of the tamping terminus from the cannula; as set forth in column 13, lines 53-56.

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With respect to claims 64,66,67,69-73,114,129,132-36,142,144, Moskovitz et al disclose all the limitations, as set forth in column 13, lines 40-59, and as best seen in FIGS 20,21.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 65,74,79-83,85-91,96-100,102-107,112,115,117-122,127,130,137,196-201 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moskovitz et al (5,741,261) in view of Bhatnagar et al (WO 00/54705).

With respect to claims 74, 79,98,122, 137, it is noted that Moskovitz et al did not teach of a delivery device to convey material into the cannula, as claimed by applicant. However, in a similar art Bhatnagar et al., pages 11, 12, evidence the use of a delivery device to permit fluid flow into the material conduit of the cannula.

Therefore, given the teaching of Bhatnagar et al., it would have been obvious to one having ordinary skill in the art at the time the invention was made to use a delivery device, as taught by Bhatnagar et al, to permit fluid flow into the material conduit of the cannula.

With respect to the rest of the above claims, the combination of references teaches all the limitations as set forth in their respective specifications and drawings.

Allowable Subject Matter

Claims 68,75-78, 84, 92-95,101,108-111,116,124-126, 131,138-141,145-195 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Amendment

Applicant's arguments with respect to claims 9-17 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

5,972,015 Scribner et al. 10-1999

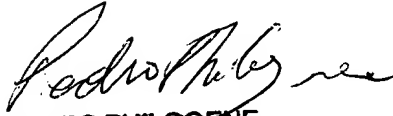
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (703) 308-2252. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gene Mancene can be reached on (703) 308-2696. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3579 for regular communications and (703) 305-3591 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Pedro Philogene
August 21, 2002



PEDRO PHILOGENE
PRIMARY EXAMINER